U.S. Application No.: 10/728,653
AMENDMENT A

Attorney Docket: 3968-099

REMARKS

Applicants wish to thank the Examiner for indicating the subject matter of claims 12 & 13 is allowable. This Amendment is responsive to the Office Action mailed November 28, 2006 (hereinafter "Office Action"). In the Office Action, claims 1-11, 14, 15 and 17-23 were rejected and claims 12 & 13 were rejected for being dependent on a rejected claim. By this Amendment, claims 1, 6 & 21 is amended, claims 4 & 5 are cancelled, and claims 24 & 25 are added. No new matter is added.

Claim Amendments

Claim 1 is amended to incorporate the subject matter of claims 4 & 5. Claims 6 & 21 are amended so that they now depend on claim 1 instead of canceled claims 4 & 5. No new matter is added.

New Claims

Claims 24 & 25 are independent claims drawn to the subject matter of claims 12 & 13, respectively. These claims should now be in condition for allowance. No new matter is added.

Specification

As noted by the Examiner, paragraph [0068] of the specification, which corresponds to paragraph [0081] of the published application, incorrectly identified U.S. Patent Application Publication 2001/0024678. Applicants adopt the suggestion of the Examiner. No new matter is added.

Claim Rejections – 35 U.S.C. § 102(b)

The Office Action states that claims 1-3, 7-11, 14, 15, 18-20, 22 and 23 are rejected under 35 U.S.C. § 102(b) as being anticipated by USP 5,370,864 issued to Peterson *at al.* (hereinafter "Peterson").

As demonstrated by the fact the Peterson rejection does not reject claims 4 or 5, Peterson neither discloses nor suggests the subject matter of claim 4 or claim 5. Since the subject matter of both claims 4 and 5 is now incorporated into claim 1, Applicants respectfully request withdrawal of the Peterson rejection.

The Office Action states that claims 1, 4, 5, 6, 14, 17 and 21 are rejected under 35 U.S.C. § 102(b) as being anticipated by USP 5,780,056 issued to Akamatsu *at al.* (hereinafter " Akamatsu").

Before reviewing the cited reference, Applicants wish to review the claimed invention as recited in amended claim 1:

> 1. (Currently amended) A spherical capsule comprising a liquid core and a seamless solid shell surrounding said core, wherein
> - the capsule has a diameter in the range of 4 - 8 mm,
> - the shell has a thickness in the range of 20 - 200 μm,
> - the shell thickness to capsule diameter ratio is in the range of 0.004 - 0.04,
> - the shell comprises 70 - 90 % (m/m) gelatin and 10 - 30 % (m/m) plasticizer, based on the solids content of the shell, and
> - the core has a flavoring content in the range of 1 - 100 % (m/m), based on the total mass of the core, wherein the shell comprises (a) a gelatin having a Bloom value of at least 200 and (b) a gelatin having a Bloom value of 0, a fish gelatin having a Bloom value of ≤ 200, or both.

The claimed invention is drawn to a spherical capsule, which includes a very thin shell surrounding a relatively large core, *see* Figure 1 below. As claimed, the shell is a mere 20-200 μm thick, while the diameter of the entire capsule (D) is between 4,000 and 8,000 μm. As a result, the diameter of the claimed core is between 3,600 μm and 3960 μm for a 4,000 μm diameter capsule and between 7,600 μm and 7960 μm for a 8,000 μm diameter capsule. Thus, while the shell thickness to capsule diameter ratio ranges from 0.004-0.04, the ratio of core diameter to the capsule diameter ranges from 0.90 [3600 μm /4000 μm] to 0.995 [7960 μm -8000 μm], *i.e.* 45/50 to 49.75/50.

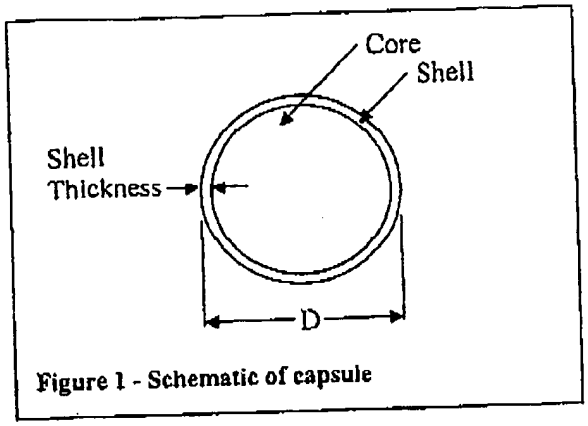


Figure 1 - Schematic of capsule

The spherical capsule of the claimed invention has a shell that includes (a) a gelatin having a Bloom value of at least 200 and (b) a gelatin having a Bloom value of 0, a fish gelatin having a Bloom value of < 200, or both. The fact the claimed gelatin shell formulations were both stable during handling and rapidly soluble in the mouth was surprising, even to the Applicants, *see* Specification, paragraphs [0044] & [0051].

Akamatsu is drawn to microcapsules of a multi-core structure. The microcapsules comprise a plurality of core particles made of a core material that include a natural carotenoid and an edible oil. The core particles have a mean particle size of 0.01 – 5 μm. The microcapsules also include a "wall" that is made of an aqueous coating material based on gelatin with a jelly strength of at least 100 bloom. The microcapsules have enough strength to protect the natural carotenoid from oxidation and deterioration. *See* Akamatsu, Abstract.

Akamatsu points out that is it particularly important that the microcapsule coating material exhibit strength sufficient to prevent the cartenoid from being oxidized or deteriorated for a long time and to be blended in tablets or the like in a stable manner, *see* Akamatsu, col. 2, ln. 9-11. This requires using gelatin with a jelly strength of at least 100 bloom, *see* Akamatsu, col. 2, ln. 34-35 & 56; col. 3, ln. 64 – col. 4, ln. 19.

~~While the jelly strength of the gelatin coating is important, so is the configuration of the~~ capsule. The Akamatsu microcapsules contain a plurality of small core particles disposed within

the coating, *see* Akamatsu, Fig. 1, and col. 5, ln. 57-59. The Akamatsu microcapsules have a mean particle size of 50 to 3,000 μm, see Akamatsu, col. 4, ln. 50-51. Akamatsu discloses that the ratio of mean particle size of the core particles to the mean particle size of the microcapsules is preferably 1/50 or less and more preferably 1/100 or less, *see* Akamatsu, col. 4, ln. 57-60. Akamatsu teaches that this ratio is critical to the strength of the capsules, *see* Akamatsu, col. 4, ln. 59-60. In contrast to the multi-core capsules of Akamatsu, the claimed invention exhibits a ratio of mean particle size of the core particles to the mean particle size of the microcapsules within a range of 45/50 to 49.75/50. Clearly, Akamatsu does not anticipate the claimed invention.

Akamatsu teaches that a mixtures of gelatins exhibiting a desirable level of strength must have a jelly strength of at least 100 bloom when the core particle diameter to microcapsule diameter ratio is 1/50 or less. Clearly, the claimed combination of gelatins for a microcapsule with a core particle diameter to microcapsule diameter ratio of at least 45/50 is neither disclosed nor suggested by Akamatsu. Accordingly, Applicants believe that claim 1 and all claims dependent thereon are drawn to allowable subject matter.

Conclusion

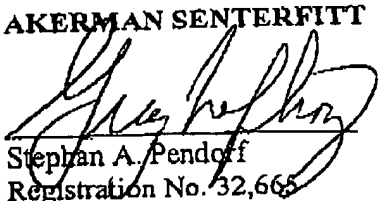
The Commissioner is hereby authorized to charge the $120 fee for a retroactive one-month extension of time and the $200 fee for an additional independent claim to Deposit Account No. 50-0951. No additional fees are believed due; however, the Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, to Deposit Account No. 50-0951.

Favorable consideration and early issuance of the Notice of Allowance are respectfully

requested. Should further issues remain prior to allowance, the Examiner is respectfully requested to contact the undersigned at the indicated telephone number.

Respectfully submitted,

AKERMAN SENTERFITT



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